sterilization of the lumen of a medical instrument, said device comprising a vessel for containing an antimicrobial solution, and means for connecting said vessel to the end of said lumen to provide antimicrobial vapor directly to the lumen during the solution vapor sterilization said device being sealed from the ambient atmosphere except through said means for connecting and containing a known quantity of antimicrobial solution.

C 2 cont.

REMARKS

This Amendment is being filed under certificate of mailing as indicated. A Notice of Appeal and Petition for Extension of Time extending the term for response through and including December 21, 1991 accompany this Amendment and are also filed under certificate of mailing.

Initially, the Official Action refers to objections to the drawings under 37 C.F.R. § 1.83A. The objection states that the flexible pouch with one opening is not shown. Contrary to the assertions of the Office Action, Applicants refer the Examiner to Figures 3 and 3A wherein there is shown a pouch having a single opening as called for in the claims. Therefore, the drawings do, in fact, comply with the Rules.

Claim 17 has been rejected under the 35 U.S.C. §112, fourth paragraph, as being an improper dependent form. It is stated that Claim 11 is limited to a vessel with a single opening which is otherwise close to the ambient atmosphere. The limitation of Claim 17, however, relates to a device according to Claim 11 which includes a second opening for releaseably attaching a cartridge containing a measured aliquot of antimicrobial solution. This structure is intended to remain close to the ambient atmosphere as called for in Claim 11. The ampule of antimicrobial solution seals off the opening and is provided as a source of antimicrobial solution. Claim 11 has been amended in order to specifically call

for the antimicrobial solution present in the vessel. This presence is acquired by use of the ampule in Claim 17. Therefore, it is respectfully submitted that Claim 17 is fully allowable.

Claim 15 has been rejected under 35 U.S.C. §102(b) as being anticipated by Wyka. Claim 15 is ultimately dependent on Claim 11 and calls for the further limitation that the bushing comprises a plurality of inwardly extending plastic flaps. The Examiner has referred to Figures 2-4, elements 80 and 82 in the Wyka reference. However, the items referred to in the Wyka reference are specifically described at Column 3, Line 20 as resilient closure flaps 80 and 82 being provided within a said opening to function in combination as a check valve to permit unidirectional communication from without to within in said cartridge (Column 3, Lines 20-23). Clearly, the flaps do not form a bushing for sealing the opening. Claim 14 which describes the bushing which is further limited by Claim 15 states that the means for connecting a vessel to a lumen comprises a flexible bushing disposed within the opening of the vessel for receiving one end of said article. The check valve of the Wyka reference does not receive an end of the article, rather its sits adjacent to the end of the article and acts as a unidirectional flow element. It does not act as a sealing element as the structure of the present claim. In the present claim, the lumen of the article to be sterilized is received by the flexible members of the bushing in order to form a sealed attachment to the lumen. Thus, the Wyka reference is easily distinguished from the claims of the present application.

Claims 11-15 and 19-22 have been rejected under 35 U.S.C. §102(e) as being anticapated by McGregor et al.

Claim 11 has been amended in order to specifically state what was believed by Applicants to be inherent in the claim itself but not actually stated. That is, the claim has been amended to add a specific reference to the vessel containing an antimicrobial

solution. This was clearly the intent of the claim language, however, the explicit statement was not present.

The McGregor reference relates to a fluid transfer device. The fluid transfer device has a cannula for piercing a stopper and a surrounding shroud to guide the cannula during the piercing operation in a manner to provide the cannula entry into the device to be close to the central axis. The guide guides the cannula during the piercing operation and the cannula pierces the stopper at the top of the device. After this, the cannula is driven down into the liquid in order to remove a lysed blood sample from the device.

Claim 11 of the present application specifically calls for a device for delivering antimicrobial vapor to the lumen of an article during solution vapor sterilization. Thus, the device of the present application is concerned with the provision of a vapor to a lumen, not the removal of liquid lysed blood samples as in the reference cited. To this end, the claim specifically calls for the vessel to contain a known quantity of antimicrobial solution for vapor formation. The McGregor reference does not contain such a substance and, in fact, contains a blood sample rather than an antimicrobial solution. Furthermore, the claims even prior to the amendment stated that the device was for delivering antimicrobial vapor to the lumen of an article. The McGregor reference, however, is specifically related to removing liquid samples once they have been centrifuged in order to separate them. Clearly, the functions are different of the two apparatuses.

Similarly, Claim 20 states that the device is for attachment to the lumen of a medical instrument and for use in enhancing solution vapor sterilization. The device comprises a vessel for containing an antimicrobial solution and means for connecting the vessel to the end of the lumen. The vessel itself contains a known quantity of an antimicrobial solution. Again, the amendment merely

explicitly states what has been inherent in the claim all along, that is the fact that the vessel contains an antimicrobial solution which is used as a precursor for a chemical vapor sterilization process. Claim 20 is, therefore, distinguishable from McGregor for the reasons described above in connection with Claim 11. That is, the provision in Claim 20 for the containing of a known quantity of antimicrobial solution as well as the provision of the apparatus for providing vapor sterilization when McGregor is specifically related to removing liquid blood samples.

Claim 18 has been rejected under 35 U.S.C. §103 as being unpatentable over McGregor et al. Claim 18 calls for the device of Claim 11 wherein the vessel contains a porous absorbent substrate for containing the antimicrobial solution. The features of Claim 11 are not anticipated by or made obvious from the McGregor reference. For the reasons described above, Claim 11 distinguishes McGregor, therefore, Claim 18 with its additional limitation that the antimicrobial solution is contained on a porous substrate cannot be said to be made obvious. The McGregor reference is specifically related to a device for separating blood samples in a centrifuge operation. Clearly, in order to separate blood in a centrifuge operation, one would be removing as many obstructions as possible from that separation. Therefore, the provision for a porous substrate within the device of McGregor is wholly inconsistent with the intent of the McGregor device and, therefore, cannot be said to be obvious from the teaching of McGregor.

For the reasons described above, it is respectfully submitted that the claims of the present application are fully allowable over the references cited. The Office Action has been made final. It is respectfully submitted that even if the Examiner disagrees with

Applicants' position that claims are allowable in their present form, the Amendment should still be entered in order to narrowly define the issues necessary for appeal. Early notice of allowance, however, is respectfully requested.

Respectfully submitted,

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